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EXAMINER

FOX, DAVID T

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 10/22/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/821,879

Applicant(s)

Kernicle et al

Examiner

FOX

Group Art Unit

1638

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

-3-

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

8/1/02

- ☒ Responsive to communication(s) filed on \_\_\_\_\_
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-68 is/are pending in the application.
- Of the above claim(s) 6-8, 18-20, 36-38, 51-58 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-5, 9-17, 21-35, 39-50, 59-68 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
  - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

6

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) \_\_\_\_\_
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

Office Action Summary

Art Unit: 1638

Applicant's election without traverse of Group I in Paper No. 10 is acknowledged. Claim 35, erroneously assigned to Group II in the restriction requirement of 3 July 2002, is hereby reassigned to Group I. Claims 1-5, 9-17, 21-35, 39-50 and 59-68 are examined in the instant office action, to the extent that they read on the elected invention, namely a non-transgenic diploid female recipient maize plant comprising a cross-incompatibility trait.

Claims 67-68 are objected to for depending upon non-elected claims.

The application should be reviewed for errors. Errors appear, for example, in claim 59, line 3, in the recitation of "the a".

Claims 14, 26, 33, 45 and 65 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend upon another multiple dependent claim. See MPEP § 608.01(n). In the interest of compact prosecution, the claims have been examined. Such treatment does not relieve Applicants of the responsibility to respond to this objection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 9-14, 27-35, 48-50, and 68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Dependent claims are included in all rejections.

Claim 1 is indefinite in its recitation of "TCB" as the abbreviation does not adequately define what is intended. The term should be completely recited in at least its first recitation. The following amendment to claim 1 would obviate this rejection:

Art Unit: 1638

In claim 1, replace "TCB" with --Teosinte Crossing Barrier (TCB)--.

Claim 27 is indefinite in its recitation of "derived from" as the degree of derivation, i.e. changes in sequence, etc. are not specified. Deletion of "derived" would obviate this rejection.

Claim 48 is indefinite in its recitation of "the inbred maize plant of claim 39" which is confusing, since claim 39 is drawn to a process rather than a plant. If intended, replacement of "39" in claim 48 with --47-- would obviate this rejection.

Claim 68 is indefinite in its recitation of "in a field being used in hybrid seed production" which appears to be an intended use rather than a positive recitation of a required claim element. It is unclear whether the field might be used for hybrid seed production some time in the future, or whether the field is currently being used for hybrid seed production of a crop other than maize. If intended, the claim should be redrafted to recite positive method steps involving crossing the cross-incompatible inbred maize with another plant to produce a hybrid maize plant.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 27 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel plants. Since the plant is essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise

Art Unit: 1638

be readily available to the public. If the plant is not so obtainable or available, the requirements of 35 USC 112 may be satisfied by a deposit of the plant. A deposit of 2500 seeds of each of the claimed embodiments is considered sufficient to ensure public availability. The specification does not disclose a repeatable process to obtain the plant and it is not apparent if the plant is readily available to the public. It is noted that applicants have deposited the plant but there is no indication in the specification as to public availability. Since the deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

Claims 1-5, 9-17, 21-35, 39-50 and 59-68 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to any maize plant comprising any "TCB trait" conferred by any DNA (claim 1), any "*Tcb locus*" (claim 10), any "gene cluster" (claim 9), any "gene which encodes for a silk effect function" (claim 12), any "gene which encodes for a pollen effect function" (claim 13), and any "modifier gene" (claim 14). In contrast, the specification only provides guidance for an inbred maize plant W22 containing a particular teosinte crossing barrier

Art Unit: 1638

genetic factor from teosinte accession no. 48703 including *Tcb1* on chromosome 4 at a particular location, namely W22-TCB deposited as ATCC No. PTA-1601, and methods for its use. No guidance is provided for the identification or characterization (even regarding its location on a particular region of a chromosome) of any other TCB trait or *Tcb* locus; or for the identification, isolation or characterization (regarding gene number or gene location) of any “gene cluster”, “silk effect” gene(s), “pollen effect” gene(s), or “modifier gene(s)”.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention “requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that “naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.” *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to “visualize or recognize the identity of the members of the genus.” *Id.*

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus as broadly claimed. Given the lack of written description of the claimed products, any method of using them would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been

Art Unit: 1638

in possession of the claimed invention at the time of filing. See Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111).

See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Claims 1-5, 9-17, 21-35, 39-50 and 59-68 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to deposited inbred maize line W22-TCB (ATTC No. PTA-1601) comprising a particular crossing barrier from teosinte accession no. 48703, does not reasonably provide enablement for claims broadly drawn to any maize plant containing any TCB trait, any *Tcb* locus, any "modifier gene", any "pollen effect" gene, or any "silk effect gene", or methods of using them. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to any maize plant comprising any "TCB trait" conferred by any DNA (claim 1), any "*Tcb* locus" (claim 10), any "gene cluster" (claim 9), any "gene which encodes for a silk effect function" (claim 12), any "gene which encodes for a pollen effect function" (claim 13), and any "modifier gene" (claim 14); molecular methods for analyzing DNA (claims 60-68); and methods for introgressing the non-exemplified (or exemplified) TCB genetic factor(s) into other plants of a multitude of genetic backgrounds (claims 39-50).

Art Unit: 1638

In contrast, the specification only provides guidance for an inbred maize plant W22 containing a particular teosinte crossing barrier genetic factor including *Tcb1* on chromosome 4 at a particular location, namely W22-TCB deposited as ATCC No. PTA-1601, and methods for its use. No guidance is provided for the identification or characterization (even regarding its location on a particular region of a chromosome) of any other TCB trait or *Tcb* locus; or for the identification, isolation or characterization (regarding gene number or gene location) of any "gene cluster", "silk effect" gene(s), "pollen effect" gene(s), or "modifier gene(s)". In addition, no guidance is provided for the introgression of the exemplified or non-exemplified TCB trait into any other genetic background, and no guidance is provided for the design of molecular probes or other techniques for the analysis of DNA containing non-exemplified and/or uncharacterized genes or genetic factors involved in the TCB trait.

The identification and localization of genes involved in cross-incompatibility in maize is unpredictable. Ashman teaches that past reports indicating the location of the Ga9 cross-incompatibility locus on chromosome 4 were not substantiated (see, e.g., page 50, top, fourth and fifth paragraphs; paragraph bridging pages 50 and 51). Bianchi et al teach that past efforts to locate the Ga8 cross-incompatibility locus were hindered by the use of linkage maps based upon inapplicable parent lines (see, e.g., page 345, bottom paragraph).

The molecular marker-based and/or linkage analysis-based localization of genes in maize is generally unpredictable. Goldman et al teach that different linkage maps are generated when different breeding lines are used as parents (see, e.g., page 909, column 2, top paragraph;



Art Unit: 1638

paragraph bridging pages 911 and 912; paragraph bridging pages 912 and 913). In addition, inconsistent results were observed regarding the correlation of particular quantitatively inherited traits (see, e.g., page 910) analogous to “pollen effect”, “silk effect”, or “modifier” genes.

Furthermore, the expression of cross-incompatibility genes in different genetic backgrounds is unpredictable. See, e.g., page 27 of the specification, top paragraph, where a breakdown in cross-incompatibility was observed, even in the exemplified W22-TCB plant, due to “attenuation” by uncharacterized “modifier genes”.

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to identify a multitude of non-exemplified TCB traits, *Tcb* loci, “modifier” genes, “pollen effect” genes, or “silk effect” genes; or to evaluate their ability to function as cross-incompatibility barriers in a multitude of non-exemplified maize genetic backgrounds. Furthermore, given the lack of characterization of any modifier gene, pollen effect gene or silk effect gene; and given the lack of characterization of the exemplified *Tcb1* locus or any other DNA comprising the exemplified TCB trait; undue experimentation would have been required to develop and evaluate methods for DNA analysis to identify the presence of, or to characterize said genes.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1638

Claims 1-5, 9, 14-17, 21, 26, 39-40, 45-50, 59 and 67-68 are rejected under 35 U.S.C. 102(b) as being anticipated by Rashid et al.

The claims are broadly drawn to any maize plant comprising any TCB trait, which trait is defined on page 7 of the specification as 1) failing to set seed when pollinated by plants lacking the TCB trait but setting seed when self-pollinated or pollinated by other TCB-containing plants; and/or 2) maintaining functional pollen and seed set when self-pollinated, or causing other maize plants to set seed when pollinated by plants containing the TCB trait. The claims are also broadly drawn to plants containing any “gene cluster”, any “modifier” gene, and any “pollen effect” or “silk effect” gene. The claims are also broadly drawn to any inbred or hybrid containing the TCB trait, methods for their analysis, and methods for their use including planting them in a field.

Rashid et al teach inbred and hybrid maize plants containing a trait as defined above, as well as crossing and phenotypic analysis of the progeny (see, e.g., page 130, Abstract and paragraph bridging the columns; paragraph bridging pages 130 and 131; page 131, column 3, bottom paragraph; page 132, paragraph bridging columns 2 and 3). The presence of unspecified “gene cluster”, “modifier”, “pollen effect” and/or “silk effect” genes would have been an inherent property.

Claims 1-5, 9, 14-17, 21, 26, 39-40, 59 and 67-68 are rejected under 35 U.S.C. 102(b) as being anticipated by Nelson.

Nelson teach inbred and hybrid popcorn lines containing a trait which prevents crossing with other maize types not possessing that trait, as well as crossing and phenotypic analysis of the

Art Unit: 1638

progeny, wherein the trait is useful for preventing unwanted pollen contamination in homogeneous populations of particular agronomic breeding lines (see, e.g., paragraph bridging pages 496 and 497; page 499, bottom two paragraphs; page 500, top paragraph; page 501, second full paragraph).

Claims 1-5, 9-17, 21-35, 39-50 and 59-66 are rejected under 35 U.S.C. 102(b) as being anticipated by Kermicle et al (1990).

Kermicle et al teach an inbred maize plant W22 which has been introgressed with a cross-incompatibility trait from teosinte accession no. 48703, methods of crossing it with other maize plants to produce hybrid seeds, wherein pollen from maize plants not containing the same cross-incompatibility trait set very little seed, and methods of analyzing the DNA of the plant and its progeny via linkage analysis and marker-derived mapping (see, e.g., page 399; page 401, column 1; page 405, Figures 2 and 3; page 406). The presence of modifiers, gene clusters, pollen- or silk-effect genes would have been inherent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was

Art Unit: 1638

commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 66 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over each of Rashid et al and Nelson.

The claim is drawn to maize plants comprising a TCB trait, said plants produced by a method comprising analyzing the DNA of progeny plants.

Each of Rashid et al and Nelson teach maize plants comprising a TCB trait, as discussed above. The claimed maize plants differ from the prior art plants only in their method of making. However, the use of a DNA analysis step would not confer a unique property to the claimed plants which would distinguish them from the prior art plants. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

Claims 1-5, 9-17, 21-35, 39-50 and 59-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kermicle et al (1990) taken with Nelson.

The claims are broadly drawn to inbreds and hybrids containing a TCB trait comprising a *Tcb* locus, and methods for their use to prevent pollen contamination in hybrid seed production.

Art Unit: 1638

Kermicle et al teach an inbred maize plant W22 which has been introgressed with a cross-incompatibility trait from teosinte accession no. 48703, methods of crossing it with other maize plants to produce hybrid seeds, wherein pollen from maize plants not containing the same cross-incompatibility trait set very little seed, and methods of analyzing the DNA of the plant and its progeny via linkage analysis and marker-derived mapping, as discussed above.

Kermicle et al do not explicitly teach the use of plants containing the trait to prevent pollen contamination in hybrid seed production.

Nelson teaches the advantages of using cross-incompatibility in maize to prevent unwanted pollen contamination in production fields (see, e.g., page 499, penultimate paragraph).

It would have been obvious to one of ordinary skill in the art to utilize the maize plants containing a cross-incompatibility trait taught by Kermicle et al (1990) in crosses to produce other inbreds and hybrids containing the trait, for ensuring freedom from pollen contamination in production fields of agronomically desirable genotypes, as suggested by Nelson.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

October 21, 2002

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP 100

1638  
